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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE:	:	
Fosamax Products Liability Litigation	:	1:06-md-1789 (JFK)
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<i>This Document Relates to:</i>	:	<b>ANSWER AND AFFIRMATIVE</b>
Fredericka Allen	:	<b>DEFENSES OF MERCK</b>
v. Merck & Co., Inc.	:	<b>&amp; CO., INC.;</b>
Case No: 1: 06-cv-09452-JFK	:	<b>DEMAND FOR JURY TRIAL</b>
	:	
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Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

**I. JURISDICTION AND VENUE**

1. The allegations of the first sentence of Paragraph 1 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of the first sentence of Paragraph 1. As to the allegations of the second sentence of Paragraph 1, Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey and states that it is without knowledge or information sufficient to form a belief as to the remaining allegations of the second sentence of Paragraph 1. Merck is without

knowledge as to the allegations in the third sentence of Paragraph 1, but for jurisdictional purposes only, admits that the Plaintiff seeks in excess of \$75,000.

2. The allegations of the first sentence of Paragraph 2 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied. Merck is without knowledge as to what is meant by the phrase "substantial business," so the allegations of the second sentence of Paragraph 2 are denied.

## **II. PARTIES**

3. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 3.

4. Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 4.

5. Merck admits that it is registered to do business in the State of Florida.

6. Merck is without knowledge as to what is meant by the phrase "regularly transacted," so the allegations in Paragraph 6 are denied.

7. Merck denies each and every allegation of Paragraph 7, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 7 inconsistent with that prescribing information and respectfully refers the Court to the Physician's Desk Reference ("PDR") for FOSAMAX® for its actual language and full text.

8. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 8 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 8.

9. Merck is without knowledge as to what is meant by the phrase “substantial revenue” so the allegations in Paragraph 9 are denied.

10. Merck is without knowledge as to what is meant by “consequences,” so the allegations in Paragraph 10 are denied.

### **III. SUMMARY OF THE CASE**

11. Merck denies each and every allegation of Paragraph 11, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

12. Merck denies each and every allegation of Paragraph 12.

13. Merck denies each and every allegation of Paragraph 13.

14. Merck denies each and every allegation of Paragraph 14.

15. Merck denies each and every allegation of Paragraph 15.

### **IV. FACTUAL BACKGROUND**

16. Merck denies each and every allegation of Paragraph 16, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

17. Merck denies each and every allegation of Paragraph 17, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and

market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 17 inconsistent with that prescribing information.

18. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 18 inconsistent with that prescribing information. Merck is without knowledge as to the allegations regarding Aredia and Zometa in Paragraph 18.

19. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 19 inconsistent with that prescribing information. Merck is without knowledge as to the allegations regarding Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck denies the remaining allegations of Paragraph 19.

20. Merck denies each and every allegation of Paragraph 20.

21. Merck denies each and every allegation of Paragraph 21.

22. Merck denies each and every allegation of Paragraph 22.

23. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 23.

24. Merck denies each and every allegation of Paragraph 24.

25. Merck denies each and every allegation of Paragraph 25.

26. Merck denies each and every allegation of Paragraph 26.
27. Merck denies each and every allegation of Paragraph 27.
28. Merck denies each and every allegation of Paragraph 28, except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.
29. Merck denies each and every allegation of Paragraph 29.
30. Merck denies each and every allegation of Paragraph 30.
31. Merck denies each and every allegation of Paragraph 31.
32. Merck denies each and every allegation of Paragraph 32, except that Merck admits that Fosamax product sales in 2005 amounted to approximately \$3.19 billion.
33. Merck is without knowledge as to whether Plaintiff used FOSAMAX®. Merck denies the remaining allegations in Paragraph 33.
34. Merck denies each and every allegation of Paragraph 34.
35. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX®. Merck denies the remaining allegations in Paragraph 35.
36. Merck denies each and every allegation of Paragraph 36.
37. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 37.
38. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 38.
39. Merck denies each and every allegation of Paragraph 39.
40. Merck denies each and every allegation of Paragraph 40.

41. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

44. Merck denies each and every allegation of Paragraph 44.

### **COUNTS**

#### **COUNT I: NEGLIGENCE**

45. Merck repleads its answers to Paragraphs 1 through and including 44, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

46. The allegations in Paragraph 46 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

47. Merck denies each and every allegation of Paragraph 47, including each and every allegation contained in subparts (a) through (f).

48. Merck denies each and every allegation of Paragraph 48.

49. Merck denies each and every allegation of Paragraph 49.

#### **COUNT II: STRICT LIABILITY**

50. Merck repleads its answers to Paragraphs 1 through and including 49, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

51. Merck denies each and every allegation of Paragraph 51, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

52. Merck denies each and every allegation of Paragraph 52, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.

53. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 53.

54. Merck denies each and every allegation of Paragraph 54.

55. Merck denies each and every allegation of Paragraph 55.

56. Merck denies each and every allegation of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

60. Merck denies each and every allegation of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

### **COUNT III: BREACH OF EXPRESS WARRANTY**

62. Merck pleads its answers to Paragraphs 1 through and including 61, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

63. Merck denies each and every allegation of Paragraph 63, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

64. Merck denies each and every allegation of Paragraph 64.

65. Merck denies each and every allegation of Paragraph 65.

66. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

#### **COUNT IV: BREACH OF IMPLIED WARRANTY**

69. Merck repleads its answers to Paragraphs 1 through and including 68, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

70. Merck denies each and every allegation of Paragraph 70, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

71. Merck denies each and every allegation of Paragraph 71, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.



72. Merck denies each and every allegation of Paragraph 72.

73. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 73.

74. Merck denies each and every allegation of Paragraph 74.

75. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 75.

76. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 76.

77. Merck denies each and every allegation of Paragraph 77.

78. Merck denies each and every allegation of Paragraph 78.

**COUNT V: FRAUDULENT MISREPRESENTATION**

79. Merck repleads its answers to Paragraphs 1 through and including 78, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

80. Merck denies each and every allegation of Paragraph 80, including each and every allegation contained in subparts (a) through (b).

81. Merck denies each and every allegation of Paragraph 81.

82. Merck denies each and every allegation of Paragraph 82.

83. Merck denies each and every allegation of Paragraph 83.

84. Merck denies each and every allegation of Paragraph 84.

85. Merck denies each and every allegation of Paragraph 85.

86. Merck denies each and every allegation of Paragraph 86.

87. Merck denies each and every allegation of Paragraph 87.

## **COUNT VI: FRAUDULENT CONCEALMENT**

88. Merck repleads its answers to Paragraphs 1 through and including 87, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

89. Merck denies each and every allegation of Paragraph 89, including each and every allegation contained in subparts (a) through (b).

90. Merck denies each and every allegation of Paragraph 90.

91. Merck denies each and every allegation of Paragraph 91.

92. Merck denies each and every allegation of Paragraph 92.

93. Merck denies each and every allegation of Paragraph 93.

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

## **GLOBAL PRAYER FOR RELIEF**

Merck denies that Plaintiff is entitled to any of the relief requested in her Global Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

## **AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these

affirmative defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Merck demands strict proof of all claims and allegations contained in Plaintiff's Complaint that Merck has not expressly admitted.

Further answering and by way of additional defense, Merck states as follows:

**FIRST AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the complaint is barred by the applicable statute of limitations and is otherwise untimely.

**SECOND AFFIRMATIVE DEFENSE**

The complaint fails to state a claim upon which relief can be granted.

**THIRD AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**FOURTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**FIFTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

#### **SIXTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

#### **SEVENTH AFFIRMATIVE DEFENSE**

Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the complaint. Merck anticipates more specific information regarding the identity and potential liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned in accordance with Florida law.

#### **EIGHTH AFFIRMATIVE DEFENSE**

The injuries and damages, if any, sustained by the Plaintiff resulted in whole or in part from her own comparative negligence and any damages recovered should be reduced accordingly.

#### **NINTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or another manufacturer.

#### **TENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

#### **ELEVENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

#### **TWELFTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

#### **THIRTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

#### **FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

#### **FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

#### **SIXTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

#### **SEVENTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

#### **EIGHTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

#### **NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

#### **TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

#### **TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

#### **TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

#### **TWENTY-THIRD AFFIRMATIVE DEFENSE**

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

#### **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

#### **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

#### **TWENTY-SIXTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

#### **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

All activities of Merck as alleged in the complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

#### **TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

#### **TWENTY-NINTH AFFIRMATIVE DEFENSE**

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and Florida Constitutions.

#### **THIRTIETH AFFIRMATIVE DEFENSE**

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.



### **THIRTY-FIRST AFFIRMATIVE DEFENSE**

At all times relevant herein, any product which is the subject matter of this action processed and distributed by Merck in any state in the United States was processed and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

### **THIRTY-SECOND AFFIRMATIVE DEFENSE**

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

### **THIRTY-THIRD AFFIRMATIVE DEFENSE**

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

### **THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff has not sustained an ascertainable loss of property or money.

### **THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff has not suffered any actual injury or damages.

### **THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under the doctrine of economic loss.

### **THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

### **THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

### **THIRTY-NINTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

### **FORTIETH AFFIRMATIVE DEFENSE**

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiff for any amounts received from collateral sources.

### **FORTY-FIRST AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

### **FORTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims of fraud are not pleaded with the required particularity.

### **FORTY-THIRD AFFIRMATIVE DEFENSE**

Merck has complied with requirements promulgated by and under federal law. The product at issue, FOSAMAX®, was approved pursuant to the applicable federal statutes and regulations. Such federal regulations and statutes preempt Plaintiffs' claims under state law and pursuant to Fla. Stat. § 768.1256 creates a statutory presumption that FOSAMAX® is not defective or unreasonably dangerous and that Merck is not liable

#### **FORTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff fails to state a claim upon which relief can be granted for medical monitoring or compensation for medical monitoring.

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In so much as the complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

#### **JURY DEMAND**

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York  
Dec. 15, 2006

Respectfully submitted,

HUGHES HUBBARD & REED LLP

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